



Atty. Dkt. No. 029318-0167

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bosch et al.

Title: STERILE FILTERED NANOPARTICULATE FORMULATIONS OF
BUDESONIDE AND BECLOMETHASONE HAVING TYLOXAPOL
AS A SURFACE STABILIZER

Appl. No.: 10/035,324

Filing Date: 01/04/2002

Examiner: Unassigned

Art Unit: 1615

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, within three (3) months of the mailing date of the foreign search report, and with thirty (30) days of receipt of the foreign search report.

RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Copies of U.S. Patent No. 5,747,001 and the Jacobs reference cited in the International Search Report were previously submitted with Information Disclosure Statements filed February 19, 2002 and March 18, 2002; therefore these references are not being submitted herewith.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 18, 2003

By Michele M. Simkin

FOLEY & LARDNER
Customer Number: 22428



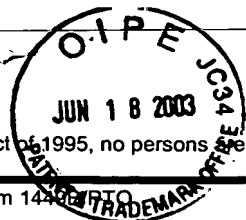
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PATENT TRADEMARK OFFICE

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| Substitute for form 1449a PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: June 17, 2003 (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/035,324 |
| | | Filing Date | 01/04/2002 |
| | | First Named Inventor | H. William Bosch et al. |
| | | Group Art Unit | 1615 |
| | | Examiner Name | Unassigned |
| | | Attorney Docket Number | 029318-0107 |

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| Sheet | 1 | of | 1 |
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| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|--------------------------|----------------------|---|--|--|--|
| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|-----------------------|-------------------------|---------------------|--------------------------------------|--|---|--|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | A1 | WO | 00/27363 | A1 | NANOSYSTEMS | 05/18/2000 | RECEIVED JUN 19 2003 TECH CENTER 1600/2900 | |
| | A2 | WO | 97/38699 | A2 | CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY | 10/23/1997 | | |
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| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A3 | OSTRANDER ET AL., "An in-vitro assessment of a NanoCrystal™ beclomethasone dipropionate colloidal dispersion via ultrasonic nebulization," <i>European Journal of Pharmaceutics and Biopharmaceutics</i> (1999), Vol. 48, No. 3, Elsevier Science Publishers B.V., Amsterdam, NL, XP004257115, ISSN: 0939-6411. | |
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|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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